

## DETAILED ACTION

1. The Examiner had several telephone conversations with the attorney, Roberte Makowski, regarding the application (see interview summary, attached). However, the Examiner had erroneously thought that the instant application had priority to 2002, because the Examiner got the application confused with a related application (10/500,377). Initially the Examiner had told the attorney that there would be no restriction requirement for lack of unity, however, when the Examiner realized that the priority date for the instant application is March. 17, 2004, then it turns out that there is prior art that applies to the instant claims. The Examiner hopes that the restriction requirement will help focus examination and attention on preferred embodiments that may have secondary considerations that will render them free of the art.

### ***Election/Restrictions***

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 2 (part a) and 10, drawn to a method for producing a transgenic plant that utilizes two expression cassettes within one DNA construct; wherein said method comprises a step of excising one of the expression cassettes.

Group II, claim(s) 2 (part b) and 10, drawn to a method for producing a transgenic plant that utilizes two expression cassettes that are on separate DNA constructs; and wherein said method comprises a step of segregation of the two expression cassettes.

Groups III-X, claim(s) 5 (in part) and 28 (in part), drawn to a method for producing a transgenic plant that utilizes a specific first compound X; wherein the specific compound X for group III is D-tryptophane, and for group IV is D-histidine, and group V is D-arginine, and group VI is D-threonine, and group VII is D-methionine, and group VIII is D-serine, and group IX is D-alanine, and group X is a derivative.

Groups XI-XVIII, claim(s) 6 (in part) and 29 (in part), drawn to a method for producing a transgenic plant that utilizes a specific second compound M; wherein the specific compound M for group XI is D-isoleucine, for group XII is D-valine, for

group XIII is D-asparagine, for group XIV is D-leucine, for group XV is D-lysine, for group XVI is D-proline, for group XVII is D-glutamine, and for group XVIII is a derivative.

Group XIX, claim(s) 7 (part a), 8 and 9, drawn to a method for producing a transgenic plant that utilizes a step of recombination by a sequence specific recombinase.

Group XX, claim(s) 7 (part b), drawn to a method for producing a transgenic plant that utilizes a step of homologous recombination.

#### **CLAIMS 1, 3, 4, AND 27 LINK THE INVENTIONS OF GROUPS I-XX**

Group XXI, claim(s) 12, drawn to a DNA construct encoding a D-amino acid oxidase with a specific consensus sequence.

Groups XXII-XXVI, claim(s) 13 (in part), drawn to a DNA construct encoding a D-amino acid oxidase that has enzymatic activity against a specified substrate; wherein the specified substrate for group XXII is D-alanine, for group XXIII is D-serine, for group XXIV is D-isoleucine, for group XXV is D-valine, for group XXVI is a derivative.

Groups XXVII-LXVII, claim(s) 14 (in part), drawn to a DNA construct encoding a D-amino acid oxidase that is described by a specific GenBank or SwissProt Accession number; wherein each invention from groups XXVII-LXVII is directed to one of the Accession numbers recited in claim 14. The Applicant is advised that if they elect one of the inventions from groups XXVII-LXVII, then they must specify which accession number their elected invention is directed to.

Groups LXVIII-LXXIV, claim(s) 15 (in part), drawn to a DNA construct encoding a D-amino acid oxidase with a specified amino acid sequence; wherein the specified sequence for group LXVIII is SEQ ID NO:2, and for group LXIX is SEQ ID NO:4, and for group LXX is SEQ ID NO:6, and for group LXXI is SEQ ID NO:8, and for group LXXII is SEQ ID NO:10, and for group LXXIII is SEQ ID NO:12, and for group LXXIV is SEQ ID NO:14.

Group LXXV, claim(s) 16 (part a), 17, 20, and 21, drawn to a DNA construct comprising a first expression cassette with recombination sites for a sequence-specific recombinase.

Group LXXVI, claim(s) 16 (part b), 18, and 19, drawn to a DNA construct comprising a first expression cassette with homology sequences A and A' having

sufficient length and homology in order to ensure homologous recombination between A and A'.

#### **CLAIMS 11 AND 22-26 LINK THE INVENTIONS OF GROUPS XXI-LXXVI**

3. Claims 1, 3, 4, and 27 link the inventions of groups I-XX. Claims 11 and 22-26 link the inventions of groups XXI-LXXVI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant applications. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP 804.01.

4. The inventions listed as Groups I-LXXVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-LXXVI is a DNA construct or method that utilizes a D-amino acid oxidase as a selection marker, and provides for excision of the selection marker or for segregation of the selection marker away from an expression cassette conferring an agronomically valuable trait.

However, in the prior art (WO 03/060133) Nasholm et al teach that D-amino acids may be used as selection markers when plants are transformed with a nucleic acid expressing a D-amino acid metabolizing protein in addition to a polypeptide that may alter the phenotype of a plant in an advantageous manner (see lines 22-31 on page 3). They teach that the D-amino acid metabolizing protein can be a D-amino acid oxidase (see line 21 on page 5).

In addition, in the prior art (PNAS (1991) Vol. 88, pp. 10558-10562) Dale et al teach that selection genes can be excised from the transgenic plant's genome (see entire article, and abstract).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to modify the methods taught by Nasholm et al to include a subsequent step of excising the selectable marker as taught by Dale et al; alternatively, it would have been obvious to modify the method taught by Dale et al to utilize one of the D-amino acid oxidase genes taught by Nasholm et al instead of

the hpt gene, because this is a substitution of an equivalent element that was known in the art. Therefore, the technical feature linking the inventions of groups I-LXXVI does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art because it lacks an inventive step over the art.

Accordingly, Groups I-LXXVI are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one

claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is

advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHY K. WORLEY whose telephone number is (571)272-8784. The examiner can normally be reached on M-F 10:00 - 4:00, with additional variable hours before 10:00 and after 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cathy K. Worley/  
Primary Examiner, Art Unit 1638